

**DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT as of November 4, 2003**

CHAPTER 16

UNIFORM PHYSICAL PLANT EQUIPMENT AND OPERATION REQUIREMENTS

The section number for an existing regulation is noted in brackets [16.01].

The electronic copy is available at www.maine.gov/dmr/

Highlighted text indicates sections with primary changes in this version.

Title section:

The entire Chapter has been reformatted and updated to comply with the NSSP:

16.01 [15.02] Compliance

16.02 [16.01] Physical Plant Site and Arrangement

16.03 [16.02, 20.09] Floors

16.04 [16.03, 20.09] Walls and Ceilings

16.05 [16.04, 20.09] Lighting

16.06 [16.05, 20.09] Heating, Cooling and Ventilation

16.07 [16.06, 16.16, 20.10]

~~Safety of Water for Processing and Ice Production~~ renamed: Water

Sections A-E are rewritten and or reorganized for additional compliance with DHS rules

The section on Chlorine is rewritten, now (E)(3)

Redundant language in Section D removed regarding water capacity - see (B)(7)

(E)(1)(c) Needs further review

Notes: In compliance with the NSSP ice products have been added and therefore ice water rules have been consolidated into this section.

Ultraviolet rules have been added.

These rules are updated to match the Department of Human Services Bureau of Health's Drinking Water Program regulations and require added review with DHS whose rules cite 2 chlorine residual levels.

Ozonated water is not acceptable. It can create bacterial and other problems.

Chlorination: see DHS web site at <http://www.state.me.us/dhs/eng/water/swtrplcy.htm>

16.08 [16.07, 20.09] Plumbing and Related Facilities

(H) Note: Toilet doors matched to NSSP and or Maine Food Code.

16.09 [16.08, 16.12, 20.09]

Sewage

16.10 [16.09, 20.09] Insect and Rodent Control Measures

16.11 [16.10] Proper Labeling, Storage and Use of Toxic Materials

16.12 [16.11, 16.12, 20.15]

Equipment Construction for Non-food Contact Surfaces

16.13 [16.12, 16.13, 16.14]

Cleaning of Non-Food Contact Surfaces

16.14 [16.12, 20.12, 20.13, 16.14]

Condition and Cleanliness of Food Contact Surfaces

(A) Note: Question: Why Jan. 1, '89? Answer: January 1, 1989 was the first edition of this guide.

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16.15 [16.14, 16.15, 20.22]

Cleaning and Sanitizing of Food Contact Surfaces

16.16 [16.17, 16.18 (B)(6), 16.20]

Prevention of Cross Contamination

(D) Note: The use of the term “marine organisms” as defined in 12 MRSA §6001(21) is also consistent with MO Chapter X.08(D).

16.17 [16.04, 16.01, 16.05, 16.07, 16.10, 16.18]

Protection from Adulterants

16.18 [16.20]

Control of Employees with Adverse Health Conditions.

16.19 [16.20]

Personnel

16.20 [16.21]

Supervision

16.21 [16.18]

Shellstock and Shucked Shellfish Storage and Handling

Note: (C) Former DMR policy - The approved NSSP “co-mingling plan” has been added.

This permit would authorize primary dealers who apply and are permitted to commingle product.

16.22 [17.03]

Shell and Waste Disposal

16.23 [16.23]

Vehicles

Notes: Shipping vehicles must be labeled with the dealer’s name and certificate number.

A replacement type vehicle is handled under §6855 and in the same manner as other short-term problems; persons need to contact enforcement to explain the situation.

The certificate name must match the name on the wholesale seafood license, i.e., the name must match the authorized activity; use standard 3-inch instead of non-standard 4-inch letters.

(E)(7) Clarification that lack of refrigeration or ice are also basis for embargo

(F) Grammar

16.24

Shellfish Harvester Vessels.

Notes: Vessels are necessary to include in Ch 16 as some dealers have harvester vessels.

The term “container” is used to cover a broad scope of the types of possible devices used instead of “storage bins”.

The time and temperature conditions during the initial harvest are requirements to meet the time-temperature matrices in the MO Chapter XIII Option 2; also see Chapters 15 and 9.08.

16.25 [16.24]

Shellfish Shipping Conditions

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CHAPTER 16

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16.01 Compliance

Each dealer shall comply with all laws and regulations relating to shellfish handling and sanitation, including, but not limited to, the requirements specified in Chapter 15, Chapter 17, Chapter 18, Chapter 19 and Chapter 20 that are appropriate to the plant and the food being processed.

16.02 Physical Plant Site and Arrangement

- A. To be certified for shellfish handling pursuant to 12 M.R.S.A. §6856, the shellfish facility must be located on a site where the physical plant will not be flooded by high tides.
 - 1. If the physical plant is flooded by tide or other causes;
 - (a) all activities shall be discontinued immediately and resumed only after waters have receded and the building has been cleaned and sanitized,
 - (b) Any shellfish, packaging materials, including wooden crates, coming into contact with the flood waters shall be destroyed.
- B. The grounds around the certified establishment shall be free from conditions that can result in contamination of shellfish; including, but not limited to, the following:
 - 1. Dusty or bumpy roads, yards or parking lots that may constitute a source of contamination in areas where shellfish are exposed;
 - 2. Inadequately drained areas that contribute to shellfish contamination through seepage or foot-borne filth, or act as a breeding ground for insects and microorganisms; and
 - 3. Litter, improperly stored equipment, waste, refuse, or uncut weeds or grass within the immediate vicinity of the plant buildings that may act as an attractant, breeding place, or harborage for rodents, insects and other pests.
- C. If the grounds around the certified facility are bordered by grounds over which the dealer has no ability to control the conditions described in Chapter 16.02(B)(1-3) above, then proper care must be exercised in the plant, through inspection, extermination, or other means, to effectively exclude pests, dirt, and other filth that may be a source of shellfish contamination.
- D. Each type of shellfish handling activity, whether receiving and shipping, holding, shucking or packing, shall be conducted in a separate room, or in well defined separate areas within the same room.
 - 1. Shellfish packing rooms shall be of sufficient size to permit sanitary handling of the product and thorough cleaning of the equipment.
 - 2. The physical facilities shall be maintained in good repair.

16.03 Floors

- A. All floors in a certified shellfish establishment shall be constructed of impervious material, which is smooth, even surfaced, and graded to drain quickly.

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- B. All floors shall be maintained in good condition and be free from cracks or other flaws which might interfere with proper cleaning or drainage.
- C. Junctions between floors and walls shall be sealed and impervious to water.

16.04 Walls and Ceilings

- A. In rooms where shellfish are stored, shucked, packed, handled, or otherwise processed or where utensils, food handling equipment, and packaging materials are stored, washed, or handled all interior surfaces shall be impervious, smooth, easily cleanable, light colored, corrosion resistant and kept in good repair.
- B. All exterior and interior doors in a shellfish establishment shall be constructed and hung so as to open outward and to provide a tight seal sufficient to prevent the entrance of rodents or flies into the establishment.
 - 1. All doors shall be kept in good repair and if part of the contiguous wall in the processing area must be constructed in compliance with Chapter 16.04(A).
 - 2. Strip curtains shall be kept in good repair and must be constructed in compliance with Chapter 16.04(A).

16.05 Lighting

- A. Ample natural and/or artificial light shall be provided in all rooms of the shellfish establishment.

16.06 Heating, Cooling and Ventilation

- A. Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- B. Mechanical refrigeration units (reefers) shall maintain temperatures at or below 45 °F, and shall be equipped with:
 - 1. automatic temperature regulating controls; and
 - 2. calibrated thermometer(s).

16.07 Water

A. Source

- 1. A certified shellfish establishment shall provide a potable water supply from an approved source that is:
 - (a) A public water system; as defined by the Maine State Department of Health and Human Services; or
 - (b) A non-public water system that is constructed, maintained and operated according to law.

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2. The potable water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

B. Quality Standards

1. Water from a public water system shall meet 40 CFR 141 - National Primary Drinking Water Regulations and the State of Maine Rules Relating to Drinking Water, CMR, 10-144 Chapter 231 and;
2. Water from a nonpublic water system shall meet state drinking water quality standards.
3. State drinking water quality standards are as follows:
 - (a) Zero (0) colony forming units of Coliform bacteria per 100 milliliters of sample;
 - (b) 10 ppm nitrate maximum; and
 - (c) 1 ppm nitrite maximum
4. All new public water systems shall test for organic, inorganic, and bacteria as required by the Safe Drinking Water Act, and obtain "new well approval" from the Department of Human Services, Drinking Water Program, or, if not a regulated Public Water System, shall sample as indicated in Chapter 16.07(B)(5).
5. Sampling
 - (a) Water from a nonpublic water system shall be sampled and tested every six months for coliform bacteria.
 - (b) Samples shall be analyzed in a laboratory recognized by the State of Maine Health and Environmental Testing Laboratory as being certified for testing for the specific parameters to be analyzed.
6. Sample Report

All past water sample results for the establishment shall be retained on file in the facility for review by the Department.
7. Capacity
 - (a) The water source and system shall be of sufficient capacity to meet the peak water demands of the facility.
 - (b) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the facility.
8. Pressure

Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water. Except in response to a temporary interruption in the approved water supply pursuant to 16.07 B 9, need not be under pressure.
9. System

Water shall be received from the source only with prior approval from the Department through the use of:

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- (a) An approved public water main; or
- (b) One or more of the following that shall be constructed, maintained, and operated according to law:
 - (i) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances;
 - (ii) Water transport vehicles; and
 - (iii) Water containers.

10. Alternative Water Supply

Water meeting the requirements specified under Chapter 16.07(A) and (B) shall be made available for a facility with a temporary interruption of its water supply through:

- (a) A supply of containers of commercially bottled drinking water;
- (b) One or more closed portable water containers;
- (c) An enclosed vehicular water tank;
- (d) An on-premises water storage tank; or
- (e) Piping, tubing, or hoses connected to an adjacent approved source.

C. Requirements for non public water supply:

- 1. The dealer shall be required to submit a water sample, testing for the presence of bacteria, nitrate and nitrite, as determined by a Department of Human Services (DHS) certified laboratory prior to certification.
- 2. The dealer shall make arrangements for Department of Marine Resources personnel or persons recognized by the Department to collect the water sample to be tested at laboratories approved or certified by the Department of Marine Resources:
 - (a) At least every ninety-days (90) while the water supply is in use;
 - (b) After the water supply has been repaired and disinfected; and
- 3. The water system shall be developed and maintained as required by the Maine Department of Marine Resources.
- 4. A report from the Department of Human Services, the Department of Marine Resources or other certified testing laboratory, which indicates the water supply is not potable, is cause for immediate suspension of the shellfish certificate for the protection of the public health.

D. Operation

- 1. Any steam used in food processing or that comes in contact with food contact surfaces shall be free from any additives, or deleterious substances consistent with federal and state laws and regulations.

E. All private water systems using continuous disinfection shall, in addition to the requirements of the rules relating to drinking water, conform to the requirements of this rule.

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1. Where continuous disinfection is required pursuant to this chapter the means of disinfection shall be measurable and shall conform to the following requirements:
 - (a) All chemical disinfectants shall be readily available;
 - (b) The residual of chemical disinfectant shall be measured and recorded daily by the user in accordance with Chapter 15.29;
 - (c) Ultraviolet light (UV) disinfection systems shall be measured as microwatts per second per centimeter squared; and
 - (d) The system shall be maintained and monitored daily.
2. Disinfectants shall be applied prior to the water storage tank or retention tank to obtain the contact time required for the specific disinfectant used.
3. If chlorination is the means of disinfection, it shall conform to the following requirements:
 - (a) Sufficient chlorine shall be added to satisfy the demand, when the well pump comes on, the chemical feed pump turns on;
 - (b) There is no bypass built into the disinfection system;
 - (c) minimum of 10 minutes of contact time before chlorinated water reaches the first customer or available tap;
 - (d) The Ct value (contact time multiplied by the free chlorine residual) for disinfection shall be four;
 - (e) The free chlorine residual entering the distribution system must be 0.2 to 0.7 milligrams per liter; and
 - (f) The dealer shall purchase a DPS method, free chlorine, low range (0 mg/l to 3.5 mg/l) chlorine test kit or appropriate testing equipment to determine the free chlorine in the water after continuous disinfection has occurred. A pool test kit is NOT acceptable.
 - (g) The dealer shall also sample, analyze and record the results of their own tests for chlorine daily. A copy of the chlorine records shall be kept on the premises for the last 2 years and shall be available for viewing by the Department in accordance with Chapter 15.29.
 - (h) Continuous disinfectant analyzers shall be connected to pump or flow controls and an alarm or automatic shutdown system such that when disinfectant falls below a pre-determined set point (e.g. minimum disinfectant residual to achieve CT for a given time period), the water system will automatically shut down and the operator shall be immediately notified.
4. If an ultraviolet light (UV) system is used as the primary means of disinfection it shall meet all of the requirements of the American National Standards Institute/National Science Foundation (ANSI/NSF) standard fifty-five for class A ultraviolet light treatment systems. An ultraviolet light system used as the primary means of disinfection shall also meet the following criteria:
 - (a) It shall be installed between the water softening equipment and the storage water equipment used to soften the water or to remove iron or manganese;

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- (b) An absolute filter size of one to two microns shall be installed prior to treatment of the water by the ultraviolet equipment.
- (c) A solenoid switch is installed so that the water system shuts down in the event of inadequate treatment.
- (d) Disinfection units shall be cleaned, serviced, and tested as frequently as necessary to maintain effective disinfection and in accordance with manufacturers instructions. Records kept of these activities must be kept of these activities in accordance with Chapter 15.29.

F. Ice Production.

- 1. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
 - (a) Be treated as food;
 - (b) Be manufactured at the certified facility from potable water in a commercial machine that has been installed in compliance with State and local plumbing code, or in another establishment approved by the Department;
 - (c) Be inspected upon receipt;
 - (d) Be stored so as not to come in contact with contaminated surfaces and shall be handled so that it will not be contaminated.
- 2. Equipment used to handle ice shall be kept clean and stored in a sanitary manner.

G. Shellstock Washing.

- 1. Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock.
 - (a) Depuration harvesters may use growing area water in the restricted or conditionally restricted classification in the open status to wash shellstock at the time and place of harvest.
- 2. If the dealer uses any system to wash shellstock, which recirculates water;
 - (a) The dealer must have all plans for construction or remodeling of a recirculating shellstock washing system reviewed and approved by the Department prior to commencing operation.
 - (b) The dealer must provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock;
 - (c) The dealer must test bacteriological water quality daily
 - (d) The dealer may use ultraviolet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the American Public Health Association (APHA) Standard Methods for the Examination of Water and Wastewater.

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- (e) Disinfection units shall be cleaned, serviced, and tested as frequently as necessary to maintain effective disinfection.
 - (f) Storage tanks and related plumbing shall be fabricated of safe materials and shall be easily cleanable.
 - (g) Tanks shall be constructed so as to be easily accessible for cleaning and inspection, to be self-draining, and to meet food contact surface requirements.
 - (h) Plumbing shall be designed and installed so that cleaning and sanitizing will be effective.
 - (i) Tanks shall be cleaned and sanitized on a regular schedule to prevent contamination of the tank and water.
3. Shellstock shall not be placed in containers of stagnant water.

16.08 Plumbing and Related Facilities

- A. The plumbing in a certified shellfish establishment shall comply with the State of Maine Plumbing Code. (02-395 CMR Chapter 238, State of Maine Internal Plumbing Rules)
- B. A satisfactory certificate of inspection from a State of Maine Certified Local Plumbing Inspector or local code enforcement officer is a prerequisite for certification of all new or added plumbing.
- C. All hose bibs, including hoses attached to faucets, must be equipped with a backflow/backsiphonage prevention device.
- D. All hoses must be stored properly when not in use; i.e. off the floor or ground.
- E. Hand washing facilities shall be provided which are:
 - 1. Convenient to work areas and located so that use by plant personnel can be readily observed by the person responsible for supervision;
 - 2. Separate from the three compartment sinks used for cleaning equipment and utensils;
 - 3. Directly plumbed to an approved sewage disposal system; and
 - 4. Provide with warm water at a minimum temperature of 110 °F (43 °C).
- F. The dealer shall provide at least one hand washing facility in the packing room for use by packing room workers unless determined otherwise by Department personnel.
- G. Each certified shellfish establishment must provide an adequate number of conveniently located toilet facilities in accordance with the Maine Plumbing Code. (02-395 CMR Chapter 238, State of Maine Internal Plumbing Rules)
- H. Toilet room doors shall be tight fitting, self-closing, and do not open directly in to a processing area.
 - 1. Toilet rooms shall be kept clean and in good repair.
 - 2. A supply of toilet tissue in a suitable holder shall be available in the toilet room.
 - 3. Ventilation shall meet state and municipal building code requirements.

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4. The hand wash sink in the toilet room shall not be substituted as a hand wash sink for other areas of the facility where the handling of shellfish or packaging materials occurs.
 - I. Supplies of soap and single service hand towels, in suitable dispensers, as well as sanitary hand dips, shall be available near hand wash and toilet facilities. Other sanitary drying devices, if approved by the Department, are also acceptable.
 1. Proper waste receptacles must be provided at each lavatory stand for disposal purposes.
 2. Hand wash and toilet facilities may not be used as storage areas of any kind.
 3. Hand washing signs that require workers to wash hands directly after using the toilet and following any work interruptions, in a language understood by the workers, shall be posted in toilet rooms and near hand wash facilities.
 4. The hand wash facility must be equipped with a mixing valve or combination faucet, and only be used for hand washing purposes.
 5. Hand wash facilities must be kept clean and in good repair.
 - J. There shall not be any cross-connections between the approved pressurized water supply and water from a non-approved source.
 1. There shall not be any fixtures or connections through which the approved pressurized water supply could be contaminated by backsiphonage.
 - (a) If booster pumps are connected directly to the potable water supply, the pumps shall be equipped with a low pressure cutoff device or an equivalent mechanism designed to prevent backsiphonage.
 - K. Depuration tanks, processing containers, and piping shall be fabricated from non-toxic corrosion-resistant materials that are easily cleanable.
 - L. Depuration tank design, hydraulics, and typical container configuration must be such that process water is evenly distributed throughout all the shellfish containers within a given tank; and
 1. Shellfish containers must allow process water to flow freely and uniformly to all shellfish within each container.
 - M. Depuration units, including depuration tanks, all reservoir tanks and related piping, shall be fabricated from safe materials, and the depuration unit construction must be such that it:
 1. is easily accessible for cleaning and inspections;
 2. is self-draining; and
 3. meets the requirements for food contact surfaces.
- 16.09 Sewage
- A. Sewage and waste water from a certified shellfish establishment shall be discharged into public sewers wherever possible. (02-395 CMR Chapter 238, State of Maine Internal Plumbing Rules, Appendix F)

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- B. Where private sewage disposal facilities must be utilized, their construction shall comply with the State of Maine Plumbing Code. (02-395 CMR Chapter 238, State of Maine Internal Plumbing Rules)
- C. All sewage and wastewater disposal facilities shall be constructed and maintained so that all wastes are inaccessible to flies and rodents.
- D. Blower and skimmer drains shall not be directly connected to sewer or other discharge lines, but shall be provided with an air gap.
- E. Refrigeration unit condensate pans shall be plumbed into the wastewater system in accordance with Maine State Plumbing Code. (02-395 CMR Chapter 238, State of Maine Internal Plumbing Rules)
- F. Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - 1. Used in shellstock storage;
 - 2. Used for food holding units (e.g. refrigeration units);
 - 3. Cleaned by hosing, flooding or similar methods; and
 - 4. Subject to discharge of water or other liquid waste.

16.10 Insect and Rodent Control Measures

- A. Insects, rodents and other vermin must not be present.
- B. The dealer shall employ such measures as are necessary to control internal and external insect and vermin including, but not limited to:
 - 1. Tight fitting, self-closing doors;
 - 2. Screening of not less than 15 mesh per inch; and
 - 3. Controlled air current.
- C. No domestic animals, fowl or pets shall be permitted in a shellfish processing plant.

16.11 Proper Labeling, Storage and Use of Toxic Materials

- A. No poisonous and toxic materials may be present in the plant, except those that are necessary for plant operation.
- B. Containers of poisonous or toxic materials shall be prominently labeled and used only in accordance with applicable federal and state laws and regulations.
- C. All such materials shall be safely stored and used only in accordance with the manufacturer's label directions.
- D. Each of the following categories of poisonous or toxic materials shall be separated from one another:
 - 1. insecticides and rodenticides;

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2. detergents, sanitizers and related cleaning agents; and
 3. caustic acids, polishes and other chemicals.
- E. Poisonous and toxic materials shall be stored in a cabinet, so labeled, in an area of the plant used for storage, except that this requirement does not prohibit conveniently locating detergents or sanitizers in equipment and utensil cleaning areas during process hours.
1. Poisonous or toxic substances shall not be stored above shellfish or food-contact surfaces.
 2. Poisonous or toxic substances shall be stored off the floor above the splash level of foot traffic.
- F. Test kits to determine strength of sanitizers shall be provided by the dealer.
- G. Sanitizing solutions other than chlorine shall not be used in the sanitizing of equipment or utensils unless the solution is approved by the Commissioner or specified in the Code of Federal Regulations, Title 21, 178.1010(36) as a safe solution for use.
- 16.12 Equipment Construction for Non-food Contact Surfaces
- A. The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned and maintained, repaired and/or replaced.
- B. The dealer shall use easily cleanable, corrosion - resistant, impervious materials, free from cracks to construct:
1. Shucking benches and tables;
 2. Shucker's chairs or stools; and
 3. Any non-food contact surfaces in shellfish storage or handling areas including, but not limited to; racks, pallets, etc.
- C. Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.
- D. Non - food contact equipment shall be maintained in good repair.
- E. Wood is not an acceptable construction material for non - food contact surfaces.
- F. Containers used for storing shellstock shall be fabricated from safe materials, cleaned and maintained in a manner and frequency as necessary to protect shellstock from contamination.
- 16.13 Cleaning of Non-Food Contact Surfaces
- A. Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.
- B. All conveyances and equipment, which come into contact with stored shellstock shall be cleaned and maintained in a manner and at such frequency as necessary to protect shellstock contamination.

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16.14 Condition and Cleanliness of Food Contact Surfaces

- A. Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment, which conforms to the Shellfish Industry Equipment Construction Guides (August 1993), U.S. Department of Health and Human Services.
- B. The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers, which are:
 - 1. Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;
 - 2. Free from any exposed screws, bolts, or rivet heads;
 - 3. Fabricated from food grade materials; and
 - 4. Kept in good repair.
- C. All joints in construction of food contact surfaces shall be welded flush and have a smooth surface.
- D. The use of enameled material and glass in utensils and equipment is prohibited. Tin or galvanized material in the food contact zone is also prohibited.
- E. Shucking containers used for the shucking of soft-shelled clams must hold a volume of ½ gallon or less.
- F. Perforations in skimmers and colanders must be smooth to facilitate cleaning.
- G. All internal angles of food contact surfaces shall be filled or otherwise fabricated to facilitate cleaning.
- H. All tanks, tubs, and other containers used for storage of shucked shellfish shall be located so that the top rim of the container is at least two feet above the floor.
- I. Compressor intakes for blowers shall be located in a protected place, and equipped with an adequate and clean filter.
- J. All containers shall be constructed of nontoxic or impervious materials, which can be easily cleaned. The containers must be designed and constructed to ensure that the contents of the container will be protected from contamination during shipping and storage.
- K. All equipment used in heat shock/hot dip processing shall meet the requirements of Chapter 16.14 (A), (B) and (C).
- L. All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements of Chapter 16.14 (A), (B) and (C).

16.15 Cleaning and Sanitizing of Food Contact Surfaces

- A. Food contact surfaces of equipment, utensils and containers shall be washed, rinsed and sanitized to prevent contamination of shellfish and other food contact surfaces.
- B. The dealer shall:
 - 1. Provide cleaning supplies and equipment;

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2. Provide three compartment sinks for equipment washing, and the sink compartments must be large enough to permit the complete immersion of the largest utensil to be sink-washed;
 3. Provide brushes, detergents and sanitizers, hot water and pressure hoses within the facility;
 4. Wash, rinse and sanitize equipment and utensils prior to the startup of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and
 5. Wash, rinse and sanitize equipment within two hours after the day's operations have ceased.
 - a. Equipment shall be air-dried.
- C. Shellfish shall be protected from contamination by washing, rinsing and sanitizing shucking containers before each filling.
- D. Containers which may have become contaminated during storage shall be washed, rinsed and sanitized prior to use or shall be discarded.
- E. Shucked shellfish shall be packed in clean containers.
- F. If used, finger cots or gloves shall be:
1. Made of impermeable materials;
 2. Sanitized at least twice daily;
 3. Cleaned more often, if necessary;
 4. Properly stored until used; and
 5. Maintained in a clean, intact and sanitary condition.
- 16.16 Prevention of Cross Contamination
- A. Shellstock shall be stored in a manner as to be protected from contamination.
- B. Shucked shellfish shall be protected from contamination.
- C. If equipment has been used for a species other than shellfish, it shall be washed, rinsed and sanitized prior to use for shellfish processing.
- D. Shellstock shall not be placed into water with any other marine organisms.
- E. Shellfish coolers shall not be used for storage of bait, other fish processing byproducts or refuse.
1. Only food grade product may be stored in the cooler physically separated from shellstock and shucked shellfish.
- F. Shellstock shall be stored in a protected location and at an adequate height off the floor to protect it from contamination from water accumulation on floor or splash by foot traffic.
- G. Employees working in both the shucking and packing activities must wash, rinse and sanitize their hands thoroughly when changing activities.

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- H. The dealer shall require all employees to wash, rinse and sanitize their hands thoroughly in a hand washing facility;
 - 1. Before starting work;
 - 2. After each absence from the work station;
 - 3. After each work interruption; and
 - 4. Any time their hands may have become soiled or contaminated.
- I. Employees handling shucked shellfish shall wear clean outer garments.
- J. Employees shall take precautions to prevent contamination of shucked shellfish from microorganisms or foreign substances, including, but not limited to, perspiration, hair, cosmetics, chemicals and medicines.
- L. In cases where an employee works in both the shucking and packing rooms, the employee shall put on a clean apron or other cover before entering the packing room.
- K. No persons other than the employees of the shellfish establishment shall be permitted in the storage, shucking, and packaging portions of the plant.

16.17 Protection from Adulterants

- A. The dealer shall operate his facility to provide adequate protection from contamination and adulteration by excluding dirt and other filth from the facility.
- B. Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing. Shellstock shall be stored in a manner as to be protected from contamination.
- C. A separate room outside the food processing area, packaging storage or shellstock/shellfish storage areas shall be provided for storage of employees' possessions, including street clothing, personal articles and breaks.
- D. Other manufacturing operations that could result in contamination of shellfish shall not be conducted in the same area where shellfish are being processed.
- E. Only materials and equipment routinely used in a specific processing activity shall be stored in the room in which the activity occurs.
- F. Sufficient space shall be provided to place equipment and to store materials in order to maintain sanitary operations and safe shellfish production.
- G. Fixtures, ducts and pipes shall not be suspended over food processing or storage areas or over areas in which containers or utensils are stored or washed.
- H. Aisles or working spaces between equipment, and between equipment and walls, must be unobstructed and sufficiently wide to permit employees to perform their duties without contaminating shellfish or food contact surfaces with clothing or personal contact.
- I. All lights, light fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are shall be of a safety type or properly shielded to prevent broken glass from contaminating the shellfish product.

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- J. Operation of cooling, heating or ventilating equipment must not create conditions that contaminate shellfish (by airborne contaminants) and shall minimize odors, vapors and condensation (including steam) in areas where shellfish is processed, stored or packed.
- K. When pesticides, rodenticides, cleaning compounds and sanitizers are used, the dealer shall apply them in accordance with applicable federal and state regulations and in such a manner to prevent the contamination of any shellfish, food contact surfaces or packaging materials with residues and must apply them in a way that does not constitute a hazard to employees.
- L. Shellfish coolers shall be constructed so they do not receive floor drainage from other portions of the plant.
- M. Shellfish storage areas shall not serve as an entryway to other areas of the facility.
- N. Shellfish shall be packed in clean containers.

16.18 Control of Employees with Adverse Health Conditions.

- A. The dealer shall take reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces.
 - 1. The diseases, which are transmissible from food workers, are those determined by the U.S. Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the Federal Register. The web site address for the Federal Register is http://www.archives.gov/federal_register/.
- B. If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single - use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions.

16.19 Personnel

- A. Employees shall not store clothing or other personal items, eat food or drink beverages, smoke, use tobacco in any form or spit in areas where shellfish are shucked, packed, stored or in areas used for washing equipment and utensils or where packaging is stored.
- B. Employees handling shucked shellfish shall wear effective hair restraints, including beard/moustache nets, and shall remove all insecure jewelry as well as any jewelry from hands that cannot be sanitized.

16.20 Supervision

- A. The holder of a shellfish certificate or his agent shall be responsible for the supervision of all activities in the shellfish facility.
- B. Supervision of all plant activities shall be provided during all hours of plant operation and shall be sufficient to ensure compliance with shellfish sanitation regulations.
- C. Lack of supervision and responsibility in an operating plant, including the non production of records required to be maintained, shall be grounds for immediate suspension of the certificate.

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- D. Supervisors shall monitor employee hygiene practices including, but not limited to those items listed in Chapter 16, sections 15(F), 16 and 17.
- E. Supervisors shall be responsible for the implementation of proper sanitation practices, including:
 - 1. Plant and equipment clean - up;
 - 2. Rapid product handling; and
 - 3. Shellfish protection from contamination.
- F. Employees shall be:
 - 1. Instructed and trained in proper food handling practices;
 - 2. Instructed and trained in personal hygiene and sanitary practices; and
 - 3. Instructed to report any symptoms of illness to their supervisor.
- G. Supervisors shall receive appropriate training in proper food-handling techniques and food protection principles and shall be trained in personal hygiene and sanitary practices.
- H. Supervisors/managers must attend any sanitation workshops/seminars offered by the Department and must pass any examinations required.
- I. All unsanitary practices shall be brought to the employees' attention by the supervisors and the employees shall be instructed on the proper practice to be used.

16.21 Shellstock and Shucked Shellfish Storage and Handling

- A. The dealer shall inspect incoming shellstock and shall reject dead or inadequately protected shellstock.
- B. Shellstock shall:
 - 1. Be reasonably free of broken shells;
 - 2. Gaping shellfish;
 - 3. Reasonably free of sediment; and
 - 4. Be packed and shipped in clean, new containers.
- C. If a primary dealer chooses to commingle shellstock, the primary dealer shall apply to the Department annually for a permit to commingle during packing, repacking or shucking
 - 1. The written application must include:
 - (a) Name (as it appears on certificate), address, telephone number and certification number included as part of a letter requesting a permit for commingling.
 - (b) A written standard operating procedure which includes:
 - (i) a detailed description of the proposed commingling plan.
 - (ii) how product is tagged or identified after commingling and,

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(iii) how commingled product is recorded in purchase and sales records.

- D. Only wholesome, live and unbroken shellstock fit for human consumption shall be shucked.
- E. Shucking containers shall:
 - 1. Be completely emptied at the packing room so that no overage is returned to the shucker; and
 - 2. Washed, rinsed and sanitized after each use.
- F. It is unlawful to use "dip buckets" in shucking shellfish or to use any container of water or other solution for the rinsing of hands or shucking knives.
- G. The certified dealer shall not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers carry shellfish from that source.
- H. The dealer shall wash, blow and rinse all shellfish meats in accordance with 21 CFR 161 section 130 (April 1, 2002).
- I. Shellfish shall be promptly shucked and packed in such a manner as to avoid contamination or exposure to any filth or impurities.
- J. Once packed, shucked shellfish shall not be soaked or washed again, by the shucker/packer or any other person.

16.22 Shell and Waste Disposal

- A. Shells and other waste materials shall be promptly and effectively removed from the shucking bench or table area to prevent interference with the sanitary operations of the shucking process.
- B. Shell and waste materials shall be disposed of such as to minimize the development of odor and not to become an attractant, harborage, or breeding place for vermin, flies or other animals.
- C. Shells and waste materials shall be disposed of in a manner that does not create a hazard for the contamination of food, food contact surfaces, ground surfaces, and water supplies.
- D. Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. Also see the DEP Waste Discharge Program web site for more information at <http://www.state.me.us/dep/blwq/docstand/wastepage.htm>.

16.23. Vehicles

- A. All trucks or other vehicles or containers on trucks used to transport shellstock or shucked shellfish, leased, owned or rented by the certified dealer shall be properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellfish product.
 - 1. Shellstock or shucked shellfish shipped under conditions creating a potential for contamination, deterioration or decomposition, for example, with boat motors, engine oil, antifreeze, dead animals, dirty tarps, etc., shall be subject to immediate embargo and/or

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destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.

- B. The cargo area of trucks, containers on trucks and other vehicles used in the shipping or transport of shellstock or shucked shellfish shall be completely enclosed and constructed and maintained in the following manner:
1. Smooth, easily cleanable, impervious and fully insulated;
 2. Doors shall close tightly;
 3. Shall have effective drainage;
 4. Kept clean with potable water and detergents, sanitizers, and other supplies for cleaning must be acceptable for use on food contact surfaces; and
 5. Shall be equipped with a functional calibrated thermometer.
 6. Trucks, containers or other vehicles must be inspected, and if approved, a decal applied by a state standardized inspector.
 7. All truck bodies must be labeled with the following information in 3" high letters, in a color contrasting with the application surface:
 - (a) name of the dealer,
 - (b) the certification number of the dealer; i.e. ME ## SS.
 8. Cats, dogs, and other animals shall not be allowed in that part of the vehicle where shellfish is stored except patrol dogs when accompanying security or police officers.
- C. Shellstock and shucked shellfish shall be transported in refrigerated trucks that maintain 45 °F (7.2 °C) or below when the shellstock have been previously refrigerated or during the months of June, July, August and September.
1. When mechanical refrigeration units are used, the units shall:
 - (a) Be equipped with automatic controls; and
 - (b) Maintain an ambient air temperature in the storage area of 45 °F (7.2 °C) or less.
 2. Any ice used to cool shellstock during transport shall meet the requirements of Chapter 16.16.
- D. When shipping time is four hours or less, the dealer shall ship all shellfish:
1. Well iced; or
 2. Refrigerated to maintain an ambient air temperature in the storage area of 45 °F (7.2 °C) or less.
 3. A time - temperature recording device is not required during shipment.
 4. Lack of ice or refrigeration shall be considered an unsatisfactory shipping condition and the shellstock and/or shucked shellfish shall be subject to embargo under Chapter 16.23(A)(1).

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E. When shipping time is greater than four hours:

1. The certified dealer shall ship all shellfish in a mechanically refrigerated conveyance which is equipped with automatic controls and maintain the ambient air in the storage area at 45° F (7.2 °C) or less; or
2. Containers with an internal ambient air temperature maintained at 45° F (7.2 °C) or below;
3. The certified dealer shall provide a time - temperature recording device to accompany each shipment of shellfish.
4. The initial certified dealer shall note the date and time on the temperature indicating device, if appropriate.
5. If a time - temperature recording device is present, each receiving certified dealer shall write the date and time on the time - temperature record, when the shipment is received and the doors of the truck or the containers are opened.
6. The final receiving certified dealer shall keep the time - temperature recording chart in his/her files and shall make it available to the Department upon request.
7. Lack of ice or refrigeration, or an inoperative time - temperature recording device shall be considered as no recording device and the shellstock and/or shucked shellfish shall be subject to embargo under Chapter 16.23(A)(1).

F. Cargo Protection From Cross Contamination

1. Shellfish Cargo Only

- (a) The entire cargo shall consist of shellfish products only.
- (b) Except for bulk shipments, shellstock shipments shall be shipped on pallets.
- (c) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.

2. Mixed Cargos

- (a) Shellfish products must be protected from contamination by the other cargo;
- (b) All cargo must be placed on pallets; and
- (c) No other cargo may be placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.

16.24 Shellfish Harvester Vessels.

A. All harvester vessel operators must ensure that any vessel used to harvest, handle, transfer and/or transport shellstock is properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock.

1. Decks and containers shall be constructed and located to prevent bilge water or polluted overboard water from coming into contact with the shellstock.
2. Bilge pump discharges shall be located so that the discharge does not contaminate shellstock.

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3. Boat decks and containers used in the harvest, handling, transfer and/or transport of shellstock for direct market shall be:
 - (a) Kept clean with potable water or water from a growing area in the approved classification or in the open status of the conditionally approved classification; and
 - (b) Provided with effective drainage.
4. Vessels and all other equipment coming into contact with shellstock during harvest, handling, transfer and/or transport shall be constructed in a manner and with materials that can be cleaned and maintained, repaired and/or replaced.
5. When necessary, clean effective coverings shall be provided on harvest boats to protect against shellstock from exposure to:
 - (a) Direct sunlight, birds; and
 - (b) Other adverse conditions.
6. Cats, dogs and other animals shall not be allowed on vessels except for patrol dogs when accompanying security or police officers.
- B. Shellstock shall be received at a certified dealer within 24 hours of harvest in accordance with the time and temperature matrices defined in Chapter 15.02(A)(91).
 1. Shellstock shall be iced or refrigerated at 45 °F (7.2 °C) or below during the months of June, July, August and September.
- C. If any ice used to cool shellstock during transfer shall meet the requirements of Chapter 16.16.
- D. Lack of ice or other acceptable means of refrigeration shall be considered an unsatisfactory transfer condition and the shellstock shall be subject to embargo under Chapter 16.23(A)(1).
- D. Disposal of Human Sewage From Vessels.
 1. Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock while the vessels are in the growing area.
 2. The Department shall educate all licensed harvesters and certified dealers concerning the public health significance of discharging human sewage overboard.
 3. An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.
 4. Portable toilets shall:
 - (a) Be used only for the purpose intended;
 - (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
 - (c) Be emptied only into a sewage disposal system;
 - (d) Be cleaned before being returned to the boat; and
 - (e) Not be cleaned with equipment used for washing or processing food.

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5. Use of other receptacles for sewage disposal may be approved by the Department if the receptacles are:

- (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
- (b) Meet the requirements in Chapter 16.24(D)(4).

16.25 Shellfish Shipping Conditions

- A. The entire cargo shall be limited to compatible molluscan shellfish products. Mixed cargo, which may include other seafoods in boxes to the same or subsequent destination, is acceptable only if the compatible molluscan shellfish products are protected from contamination by the other cargo through partitioning, horizontal separation or other isolation methods. No other cargo may be placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.
- B. Shellstock shipments shall be palletized (except in bulk). Pallets shall be used when the conveyances do not have a channeled floor. Mixed cargoes of seafood, other than shellfish, shall be palletized.